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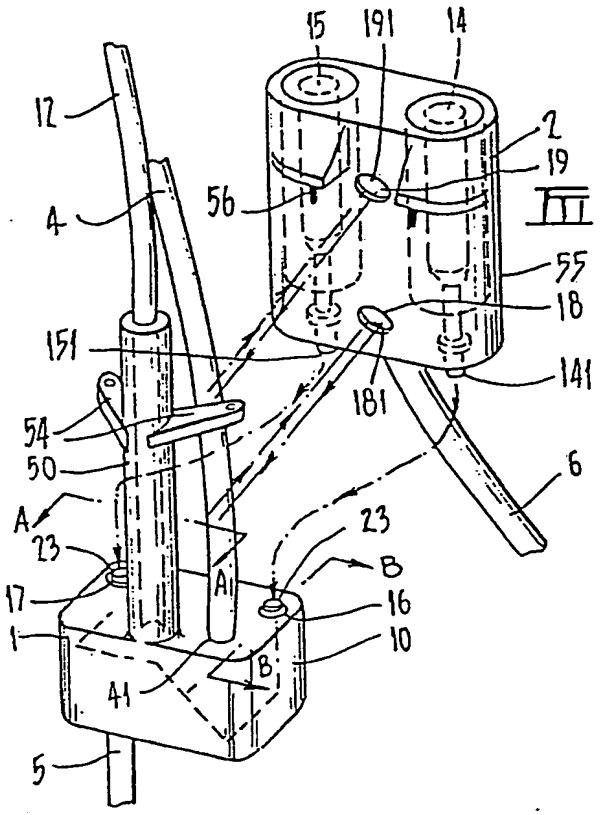
(54) Title: FLOW CONTROL FOR INTRAVENOUS SOLUTIONS

(57) Abstract

Intravenous administration apparatus comprises a chamber (10), an inlet (41) to the chamber provided with a first valve (16), an outlet from the chamber provided with a second valve (17), a first liquid level sensor (181) disposed to detect a first liquid level in the chamber, a second liquid level sensor (191) disposed to detect a second liquid level in the chamber being a level higher than the first liquid level, and control means operative in use when an intravenous solution is supplied under pressure to the inlet to perform a cycle including opening the first valve to commence filing of the chamber with the solution, closing the first valve on the solution reaching the second level, opening the second valve whereby to allow the solution to pass out of the outlet under gravity, and closing the second valve on the solution falling to the first level.



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FLOW CONTROL FOR INTRAVENOUS SOLUTIONS

This invention relates to apparatus.

In a specific instance this invention relates to apparatus for delivery of solutions to be given intravenously to an animal.

The usual method of administering intravenous solutions is via gravity feed through a valve which is to be adjusted to achieve the desired rate of flow. However, although many valves have been tried, it is commonly reported that accurate adjustment is difficult to obtain and is particularly difficult to maintain over a prolonged period. Some reasons for this difficulty to maintain a desired rate of flow over a prolonged period are changes in fluid head, changes in a patient and cold creep of plastics.

As a result, various other methods of intravenous administration have been tried including those using closely controlled metering pumps but while these may be able to adequately control flow rate the use of pumps can produce problems and hence they are considered by us to be undesirable.

Accordingly, we have sought to develop apparatus which is less prone to the above problems.

The present invention provides intravenous administration apparatus comprising a chamber, an inlet to the chamber provided with a first valve, an outlet from the chamber provided with a second valve, a first liquid level sensor disposed to detect a first

liquid level in the chamber, a second liquid level sensor disposed to detect a second liquid level in the chamber being a level higher than the first liquid level, and control means operative in use when an intravenous solution is supplied under pressure to the inlet to perform a cycle including opening the first valve to commence filling of the chamber with the solution, closing the first valve on the solution reaching the second level, opening the second valve whereby to allow the solution to pass out of the outlet under gravity, and closing the second valve on the solution falling to the first level.

Because the distance between the first and second levels will normally be maintained constant the above described apparatus will deliver a constant volume of solution per cycle and if it is supplied at the inlet with the solution at constant pressure it will cycle at a substantially constant rate.

However, as maintenance of constant pressure at the inlet is difficult and as different patients and different solutions will require different rates of feed of the solution it is preferred that rate control means is provided for controlling the cycle rate whereby a selected and substantially constant volume of the solution with respect to time can be fed to a patient.

Various methods of rate control are possible such as pressurizing the chamber above the second level to a predetermined pressure but in general electronic control of rate is preferred.

One means of rate control is to use a third valve downstream of the second valve and timing means to open the third valve at selected time intervals and for selected times.

Another means of rate control involves conditional circuit means in a circuit controlling the second valve which will result in the second valve only opening at preselected time intervals. In this instance preferred

means includes a normally open means in a circuit controlling the second valve and timer means to close that means at preselected time intervals.

Most preferably, rate control is at least in part governed by computer or micro-computer means which may control the rate of administration in response to signals derived from a patient or from a predetermined programme.

Whatever rate control means is used, it is highly desirable for accurate rate control that signals causing delivery should be maintained or be effective for a time at least equal to the time that it takes the solution to flow out of the chamber and should not be repeated more often than the time taken to refill the chamber.

The inlet may be supplied with the solution by a pump but in general a gravity feed will suffice.

It is not proposed that the solution should flow from the outlet to a patient by any means other than gravity.

It is desirable that the first level is sufficiently above the outlet to guard against the possibility of air entering the outlet and causing air embolism in a patient.

The first and second valves may be operated in any convenient way but solenoid control is currently preferred.

The apparatus of this invention is preferably in at least two separable parts; a first part desirably carries the chamber, the inlet, the outlet and the first and second valves, and a second part desirably carries means such as solenoids for operating the first and second valves and the first and second liquid level sensors. The first part may be intended for single use only and if desired may be discarded after a single use. The second part may be intended to be reusable. The second part preferably has no physical contact with the solution and hence need not necessarily be used in sterile

condition. Since the first part will have contact with the solution it is preferable that it be supplied in sterile condition.

The second liquid level sensor may be adjustable in position to vary the second liquid level and hence the quantity of the solution dispensed in each cycle. This is not essential but it is desirable as it is preferred that the solution is substantially constantly dispensed rather than substantially intermittently dispensed. This last desiderata can alternatively be met by using different first parts of different chamber volumes notwithstanding that the height difference between the first and second liquid levels may be the same.

It is not essential that the first and second valves be metering valves and in general it is preferred that they are merely on-off valves.

The liquid level sensors are preferably opto-electronic devices and may operate using transmitted or reflected light.

The sensors may include a discrete light emitter and a discrete light receptor. However, a range of units combining an emitter and receptor is currently available and these may be used if desired.

The sensors are preferably adapted to detect the passing of a meniscus.

A third liquid level sensor may be provided to shut off the apparatus if due to some fault the liquid level in the chamber should rise to a third level above the second level.

A specific construction of apparatus in accordance with this invention and its manner of use will now be described with the aid of the accompanying drawings in which:

Fig. 1 is a schematic drawing of the apparatus as set up for use,

Fig. 2 is an exploded perspective view of the apparatus,

Fig. 3 is a cross-section on line A-A in Fig. 2,

Fig. 4 is a cross-section on line B-B in Fig. 2,

Fig. 5 is a schematic circuit diagram of part of the apparatus,

Fig. 5a is a schematic representation of part of the apparatus described above,

Fig. 6 is a block diagram of part of electrical circuitry which may be used,

Fig. 7 is a circuit diagram of other circuitry which may be used,

Fig. 8 is a front perspective view of a first part of another apparatus,

Fig. 9 is a rear perspective view of the first part shown in Fig. 8,

Fig. I0 is a front perspective view of a second part of said another apparatus,

Fig. 11 is a schematic representation of portion of said another apparatus,

Fig. 12 is a flow chart illustrating the manner of operation of said another apparatus, and

Fig. 13 is a circuit diagram of said another apparatus.

The apparatus in accordance with this invention shown in Fig. 1 comprises a first part 1 and a second part 2.

The first part 1 comprises a body 10 having an inlet 41, a valve 16 downstream of the inlet, a chamber or column 50 downstream of the valve 16, an outlet 51, a valve 17 upstream of the outlet and wherein upstream of the valve 17 is connected to the column 50.

The valves 16 and 17 are both identical in construction and are shown in more detail in Fig. 4. The valves 16 and 17 have inlet ports 24 which respectively communicate with the inlet 41 and the column 50, outlet ports 25 which respectively communicate with the column 50 and the outlet 51 and valve closure means comprising an elastomeric body 22 located in a chamber 26 and an operator 23. In use, pushing down on operator 23 will deform the body 22 downwards with respect to Fig. 4 and

in so doing the body 22 will narrow to allow fluid to pass from the inlet port 22 via the chamber 26 to the outlet port 25. Releasing the operator 23 will result in the body 22 resuming its former shape to close the chamber 26.

The column 50 has arms 54 for connecting the second part 2 thereto.

The second part 2 includes a body 55 having lugs 56 for connection to the arms 54. The body 55 carries solenoids 14 and 15 having cores 141 and 151, has windows 18 and 19 and carries combined diodephoto-transistor units 181 and 191.

In normal use the second part 2 is assembled to the first part 1 and in the region in which the windows 18 and 19 are located the column 50 has the form shown in Fig. 3.

As shown in Fig. 3 the column has a window 61 through which light from the diode at one end of the units 181 and 191 may pass to be reflected by a reflective surface 20 through a passing meniscus to the phototransistor of said one of the units 181 and 191 and a curved wall 21 to scatter light so that light reflected from the wall 21 will not substantially affect the phototransistor of said one of the units 181 and 191.

In use the above described apparatus and, if desired, an identical apparatus distinguished by the reference letter "a" will usually be connected to a bottle 3 containing an intravenous solution such as blood, dextrose or electrolyte mounted to a stand 7.

The bottle 3 will be connected to the inlet 41 by a tube 4, the column 50 will be provided with an air breather tube 12 and the outlet 51 will be connected to a patient by a line 5. In addition, a multicable will pass from the electronics of the apparatus to a control unit 8 and, if desired, a microprocessor 9, a recorder/printer 10 and a remote warning device 11.

The control unit 8 includes switches 71 and 72 which are normally open, means for closing those switches and timer means.

When operation is to commence the control unit 8 is operated to signal switch 71 to close.

As a result the solenoid 14 will be actuated, its core 141 will contact the operator 22 of valve 16 which will open to allow the solution to flow under gravity from the bottle 3, down the tube 4, through the inlet 41 into the column 50 and to rise in the column 50.

When the upward going meniscus of the solution in column 50 reaches the level of the unit 191 that unit will signal the control unit which will open the switch 71 to close the valve 16 and close the switch 72 to open the valve 17.

The solution in the column will then flow under gravity through the valve 17, through the outlet 51 and the tube 5 to the patient.

When the downward going meniscus of the solution in the column 50 reaches the level of the unit 181 that unit will signal the control unit which will open the switch 72 to close the valve 17.

Thereafter the control unit will repeat the sequence at controlled rate and since the distance between the units 181 and 191 is constant, constant volumes of the solution will be dispensed at controlled rate.

The microprocessor 9 might monitor body functions of the patient and vary the rate of dispensation to suit and might output to the recorder/printer 10. If the apparatus should fail the warning device 11 may be arranged to give a signal.

The first part 1 may be discarded after a single use if this is desired but the second part 2 may be re-used many times.

Various forms of control other than that described

above can be provided and when control means is considered it is of value to examine the logic which can be applied to the above apparatus and in this respect reference will be made to Figs. 5a - 7 of the accompanying drawings.

Referring now to Figure 5a, S indicates the bottle 3, X and Y indicate the valves 16 and 17, A and B indicate opto-electronic devices comprising diode emitters and diode light detectors and P indicates patient.

In this instance the devices A and B are such that their outputs are high when clear fluid is present in front of them.

In this instance the operating cycle begins when fluid fills the column 50, A and B are covered and their outputs are high. X and Y are closed.

The logic state is

LOGIC	VALVES
A B T	X Y
I I I	O O

where O and I denote respectively high and low voltages on the logic and closed and open states on the valves. T denotes a negative going trigger pulse, absent here. The device "waits" in this position.

A negative going trigger pulse T then arrives from a variable frequency oscillator. It is the frequency of this oscillator that determines the cycling frequency of the device and thus the ultimate intravenous flow rate. This frequency may be operator determined (manually controlled potentiometer) or determined automatically by a microprocessor on the basis of some physiological input. Arrival of the trigger pulse causes the opening of valve Y.

The logic state is now

LOGIC	VALVES
A B T	X Y
I I O	O I

NEGATIVE↑GOING TRIGGER PULSE

The trigger pulse then returns to the high level. Opening of valve Y causes the column 50 fluid to fall into patient P causing the output of B to go low. The logic is organised so that this causes no change in valve setting.

The logic state is now

LOGIC	VALVES
A B T	X Y
I O I	O I

The fluid thus continues to fall in the column 50 causing output of A to go low. With this change in logic, valve X is opened and valve Y simultaneously closed.

The logic state is now

LOGIC	VALVES
A B T	X Y
O O I	I O

The column 50 fluid level now rises under the influence of the head of the bottle 3. The output of A goes high. The logic is arranged so that this causes no change in valve setting.

The logic state is now

LOGIC	VALVES
A B T	X Y
I O I	I O

The fluid thus continues to rise in the column 50 causing the output of B to go high. With A and B now both high, X is closed and the device is returned to the "waiting" state, ready for a further trigger pulse.

The logic state is now

LOGIC	VALVES
A B T	X Y
I I I	O O

The cycle of operation may thus be summarised

LOGIC	VALVES	
A B T	X Y	
I I I	O O	
I I O	O I	
I O I	O I	———COLUMN 50 FLUID FALLIN

O O I	I O	
I O I	I O	———COLUMN 50 FLUID RISING
I I I	O O	

It will be noted that the logic state of A and B is identical when fluid is rising or falling in the column 50 though these states are associated with complementarily switched states of the valves X and Y. This is achieved by switching of a bistable Z which is edge triggered by changes in A and B. If the Z state is included in the truth table, the operation may be summarized.

LOGIC				VALVES	
A	B	T	Z	X	Y
I	I	I	NS	O	O
I	I	O	I	O	I
I	O	I	NS	O	I
O	O	I	O	I	O
I	O	I	NS	I	O
I	I	I	NS	O	O

Where NS denotes the not significant case.

Similar considerations apply when an opaque fluid is in front of the devices A and B excepting that their outlets are low when in that condition and this affects logic values concerning the electrical circuitry shown in Fig. 6, the outputs of electro-optical devices A and B are fed to comparators where each signal is compared to a potentiometer-set reference voltage. The reference voltage in each case is set so that the comparator changes state when the fluid meniscus crosses the associated electro-optical device. The comparator output goes high when clear fluid covers the device. In view of the dynamic "edge-triggered" nature of the logic circuitry, the comparator output is fed through a Schmitt trigger to avoid random transients of the comparator at the switching point.

The "clean" comparator signal is then fed to the

logic circuitry shown in Fig. 7. The basic logic circuitry, the operation of which is previously described is as seen in Fig. 7.

Alternatively, the logic sequence may be achieved using a microprocessor under interrupt control. There is provision for recognition and flagging of alarm states such as opening of valves X and Y simultaneously or arrival of a trigger pulse when the side arm is not refilled (A and B high).

The apparatus shown in Figs. 8 - 13 differs from that of Figs. 1 - 7 principally in that it is microcomputer controlled but also in other aspects. Where applicable, like reference numerals are used as were used in respect of Figs. 1 - 7.

The apparatus of Figs. 8 - 13 includes the first part 1 and the second part 2.

In this instance the first part 1 while differently configured to that of Figs. 1 - 7 differs principally in that the air breather tube 12 is omitted, column 50 is made as an integral part of the first part 1 and is connected at its upper end to a sealed chamber 201 which is also an integral part of the first part 1 and in that it has keying lugs 202 and a hole 203 which can be received in and receive recesses 204 and pin 205 in the rear 206 of the second part 2. Further, the second part 2 has a ball catch 207 which also serves to assist in releasably retaining the first (1) and second (2) parts together.

In this instance the first part 1 differs from that of Figs. 1 - 7 as indicated above and additionally in that it has manual override buttons 211 and 212 for the solenoids 14 and 15 and contains a battery and all control electronics such that it is a self-contained unit not needing connection to any unit other than the first part 1 unless an external power source is to be used.

The second part 2 contains the solenoids 14 and 15, the windows 18 and 19 but has separate

diodes 181a and 191a and phototransistors 181b and 191b which locate, when the first part 1 is positioned, on axes 181c and 191c on opposite sides of the column 50.

Further, the second part 2 has a front panel provided with control switches 221-226 and a four alphanumeric character display 227.

The display 227 is provided by an integrated circuit being a NSM1416.

The second part 2 also contains an alarm buzzer 228, a voltage regulator 229 which is a LM340/05, a four unit operational amplifier which is a LM339 of which only two units are used and a microprocessor which is a 6805.

The microprocessor is made by Motorala is 8-bit and has 4K of PROM.

Reference is made to Fig. 13 for the schematic electronic circuit diagram.

From Fig. 13 it should be noted that a 4MHz crystal 230 is used

and signals to the solenoids 14 and 15 are assisted by FETs which are IRF521.

Reference is now made to the schematic in Fig. 11 and the flow diagram in Fig. 12.

In Fig. 11, X and Y indicate the valves 16 and 17, A and B indicate upper and lower liquid level sensors which are constituted by the diodes 181a and 191a and associated phototransistors 181b and 191b, S indicates the bottle 3 and P indicates patient.

The microcomputer operates a programme to perform in accordance with the flow diagram of Fig. 12.

It is to be noted that operating a selected one of switches 223 and 224 will cause the rate of infusion to increase or decrease and for the so selected rate to be displayed by the display 227. Operating a selected one of the switches 225 and 226 will cause the total volume to be delivered (whereafter which volume is delivered the apparatus will be caused to turn off)

to increase or decrease and for the so selected volume to be displayed by the display 227. Operating switch 222 opens both valves X and Y to allow liquid to enter lines and purge air therefrom prior to those lines being connected to a patient.

It will also be observed from the flow diagram that the microcomputer is capable of giving alarms, display and shutting down delivery if occlusions occur in lines or if the supply S is empty.

Modifications and adaptations may be made to the above described without departing from the spirit and scope of this invention which includes every novel feature and combination of features disclosed herein.

In a modification of the above the second valve (for example, valve 17) is pulsed so as to deliver the volume of fluid in the chamber (for example column 50) over a longer period of time. Such pulsing may conveniently be achieved by pulsing the associated solenoid 15. Accordingly, if desired timer means may be incorporated into the part of the circuit supplying solenoid 15 so as to cause valve 17 to be open and closed for predetermined intervals cyclically during the appropriate part of the cycle. Indeed, by appropriately adjusting the mark space ratio of the valve 17 being open and being closed flow rates, of below 5 ml./hour can be achieved.

In another modification a third liquid level sensor is interposed between the first and second liquid level sensors at, say 2/3 rds the distance between the first and second liquid level sensors above the first liquid level sensor. Appropriate circuitry, for example switches, may be provided whereby that third liquid level sensor may not be used or be used in lieu of the first or the second liquid level sensor whereby any one of the full volume of the column 50 between the first and second liquid level sensors, 1/3rd that volume (between

the second and third liquid level sensors) and 2/3rds that volume (between the third and first liquid level sensors) may be dispensed as selected.

1. Intravenous administration apparatus comprising a chamber, an inlet to the chamber provided with a first valve, an outlet from the chamber provided with a second valve, a first liquid level sensor disposed to detect a first liquid level in the chamber, a second liquid level sensor disposed to detect a second liquid level in the chamber being a level higher than the first liquid level, and control means operative in use when an intravenous solution is supplied under pressure to the inlet to perform a cycle including opening the first valve to commence filling of the chamber with the solution, closing the first valve on the solution reaching the second level, opening the second valve whereby to allow the solution to pass out of the outlet under gravity, and closing the second valve on the solution falling to the first level.

2. Intravenous administration apparatus as claimed in claim 1, including means for supplying the inlet with said solution at constant pressure.

3. Intravenous administration apparatus as claimed in claim 1, including rate control means for controlling the rate of repetition of said cycle whereby a selected and substantially constant volume of said solution with respect to time is passed from said outlet.

4. Intravenous administration apparatus as claimed in claim 3, wherein the rate control means includes a third valve downstream of the second valve and timing means to open the third valve at selected time intervals.

5. Intravenous administration apparatus as claimed in claim 3, wherein the rate control means includes conditional circuit means operative to open the second valve at preselected time intervals.

6. Intravenous administration apparatus as claimed in claim 5, wherein the conditional circuit means includes a normally open means in a circuit controlling the second valve and timer means to close the normally open means at preselected time intervals.

7. Intravenous administration apparatus as claimed in claim 3, wherein the rate control means includes a computer.

8. Intravenous administration apparatus as claimed in claim 7, wherein the computer is adapted to control administration of said solution in response to signals derived from a patient and/or from a predetermined programme.

9. Intravenous administration apparatus as claimed in any preceding claim, wherein said solution is delivered to a patient from said outlet solely by gravity.

10. Intravenous administration apparatus as claimed in any preceding claim, wherein the first level is sufficiently above said outlet to guard against the possibility of air entering said outlet.

11. Intravenous administration apparatus as claimed in any preceding claim and in two separable parts being a first part including the chamber, the inlet, the outlet and the first and second valves and a second part including means for operating the first and second valves and the first and second liquid level sensors.

12. Intravenous administration apparatus as claimed in claim 11 when appended to claim 3 wherein the second part additionally includes the rate control means.

13. Intravenous administration apparatus as claimed in claim 11 or claim 12, wherein the second part is a reusable and wherein the first part is a disposable.

14. Intravenous administration apparatus as claimed in any one of claims 11-13, wherein the second part has no physical contact with said solution during use.

15. Intravenous administration apparatus as claimed in any preceding claim, wherein the second liquid sensor is adjustable in position whereby to vary the second liquid level and hence the quantity of said solution dispensed in each cycle.

16. Intravenous administration apparatus as claimed in

any one of claims 11-14 wherein the first part is selected from a number of such first parts each having the chamber of different volume.

17. Intravenous administration apparatus as claimed in any preceding claim, wherein the first and second valves are on-off valves.

18. Intravenous administration apparatus as claimed in any preceding claim, wherein the first and second liquid level sensors are opto-electronic devices.

19. Intravenous administration apparatus as claimed in any preceding claim and including a third liquid level sensor for shutting off the apparatus if the liquid level in the chamber should rise to a third level above the second level.

20. Intravenous administration apparatus as claimed in any preceding claim, wherein the control means is operative to shut off the apparatus if the level in the chamber does not fall to the first level within a predetermined time.

21. Intravenous administration apparatus as claimed in any preceding claim, if the level in the chamber does not rise to the second level within a predetermined time.

22. Intravenous administration apparatus as claimed in any preceding claim wherein the control means is adapted to give an alarm.

23. Intravenous administration apparatus operative in accordance with the flow diagram disclosed herein.

24. Intravenous administration apparatus substantially as hereinbefore described with reference to any one of the accompanying drawings.

25. The articles, things, parts, elements, steps, features, methods, processes, compounds and compositions referred to or indicated in the specification and/or claims of the application individually or collectively, and any and all combinations of any two or more of such.

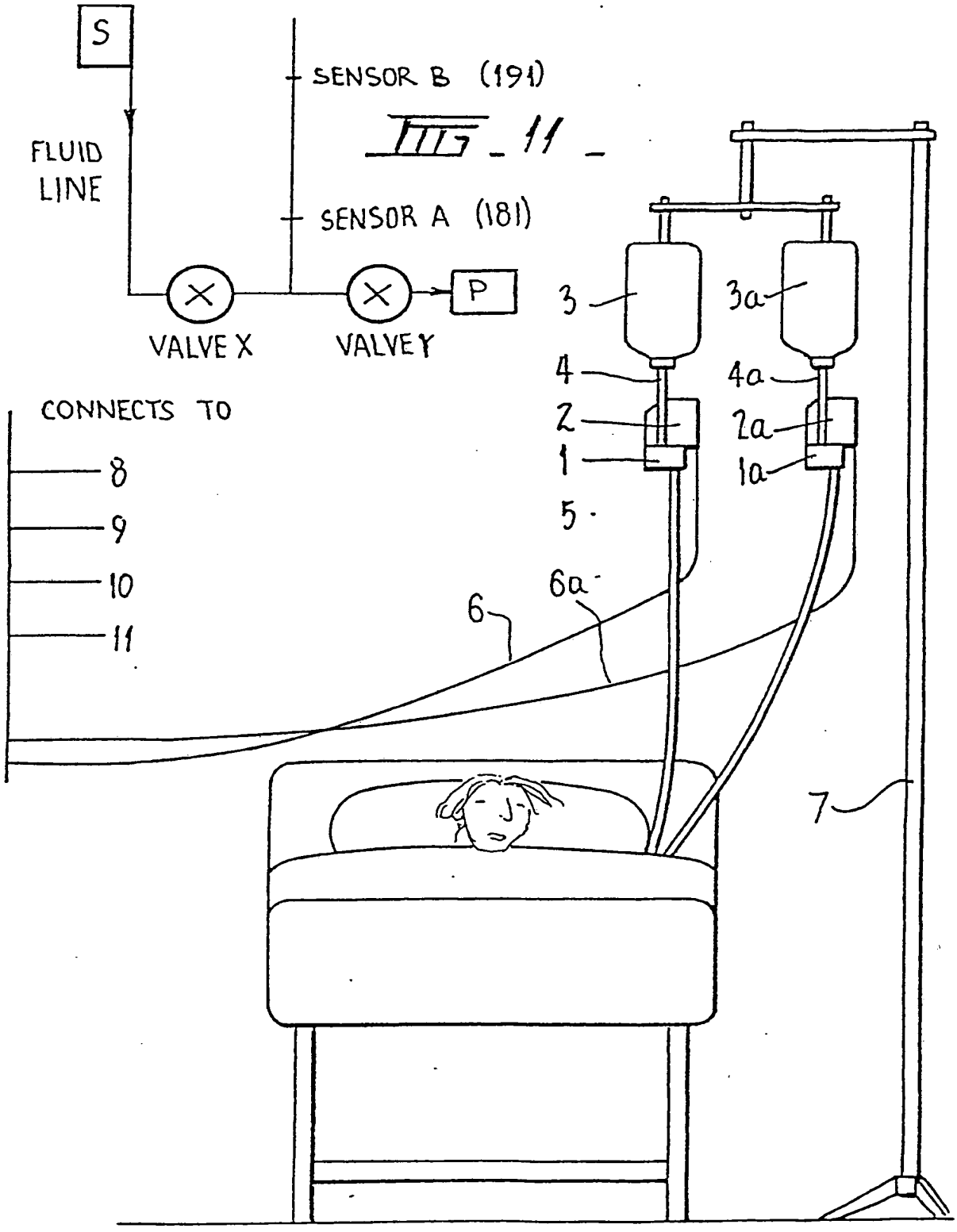


FIG - 1 -

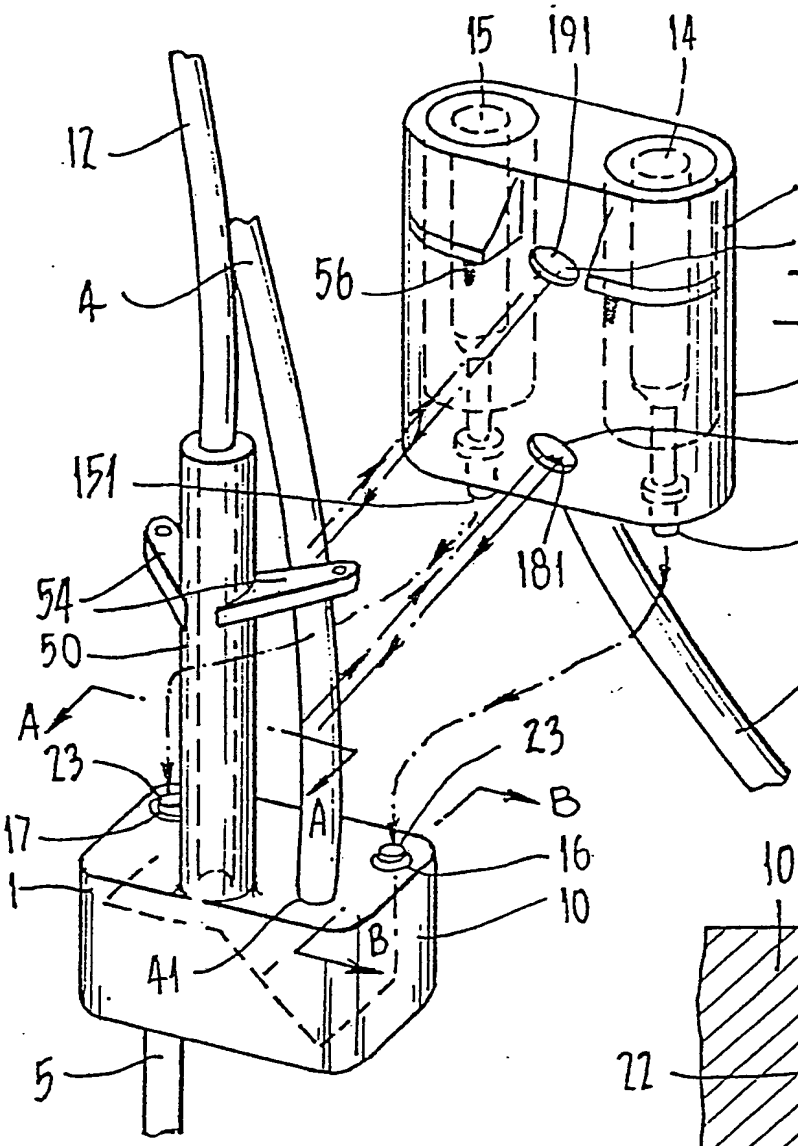


FIG. 2.

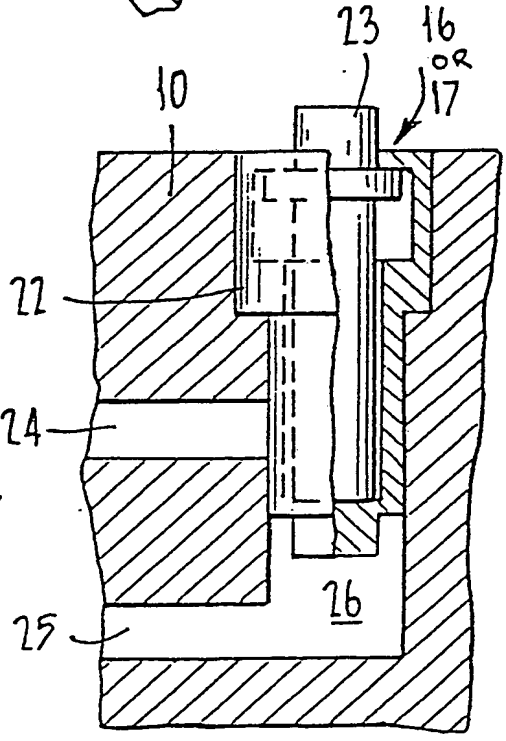


FIG. 4.

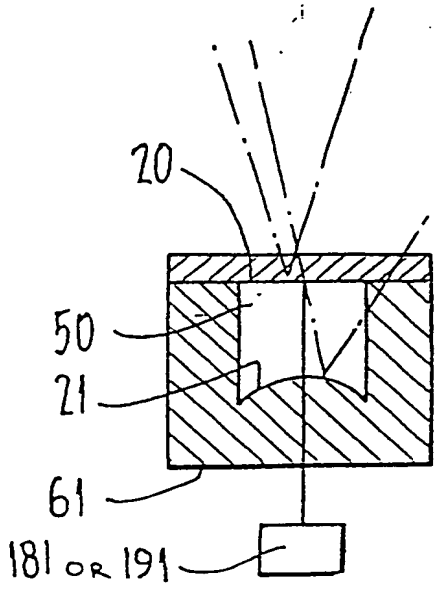


FIG. 3.

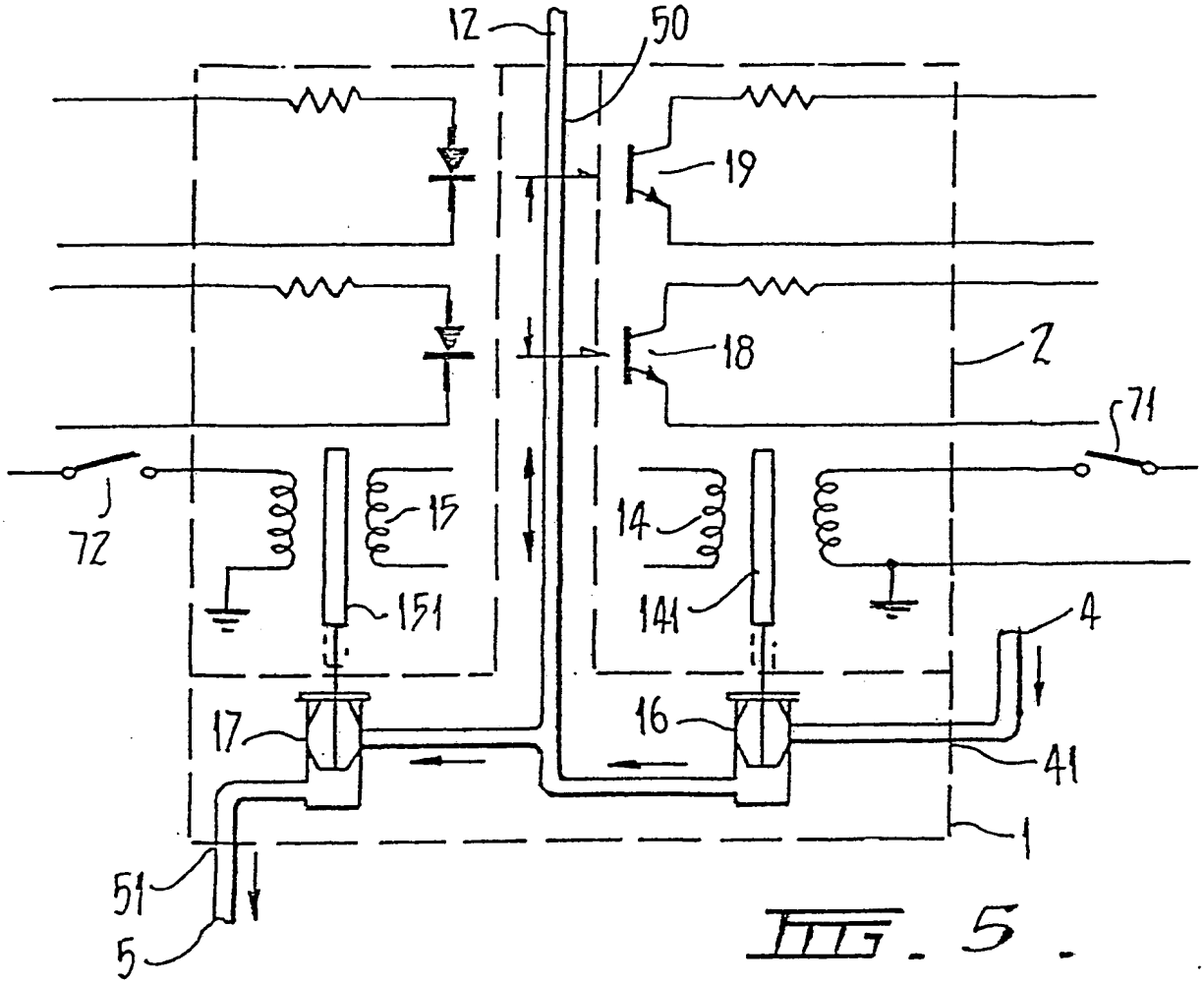


FIG. 5.

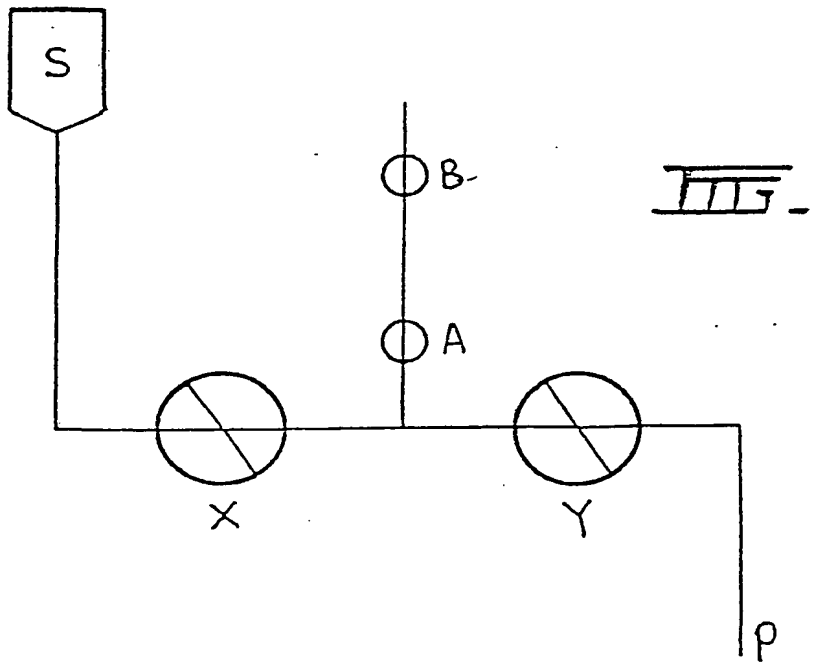


FIG. 5a.

FIG. 6.

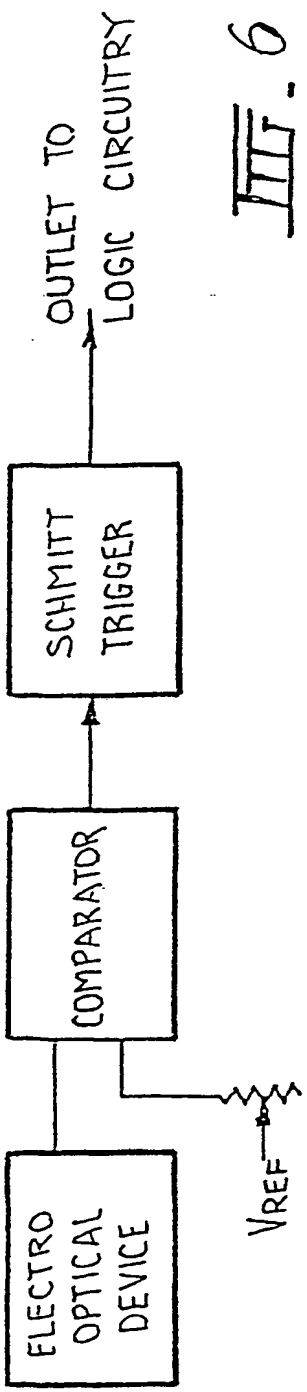
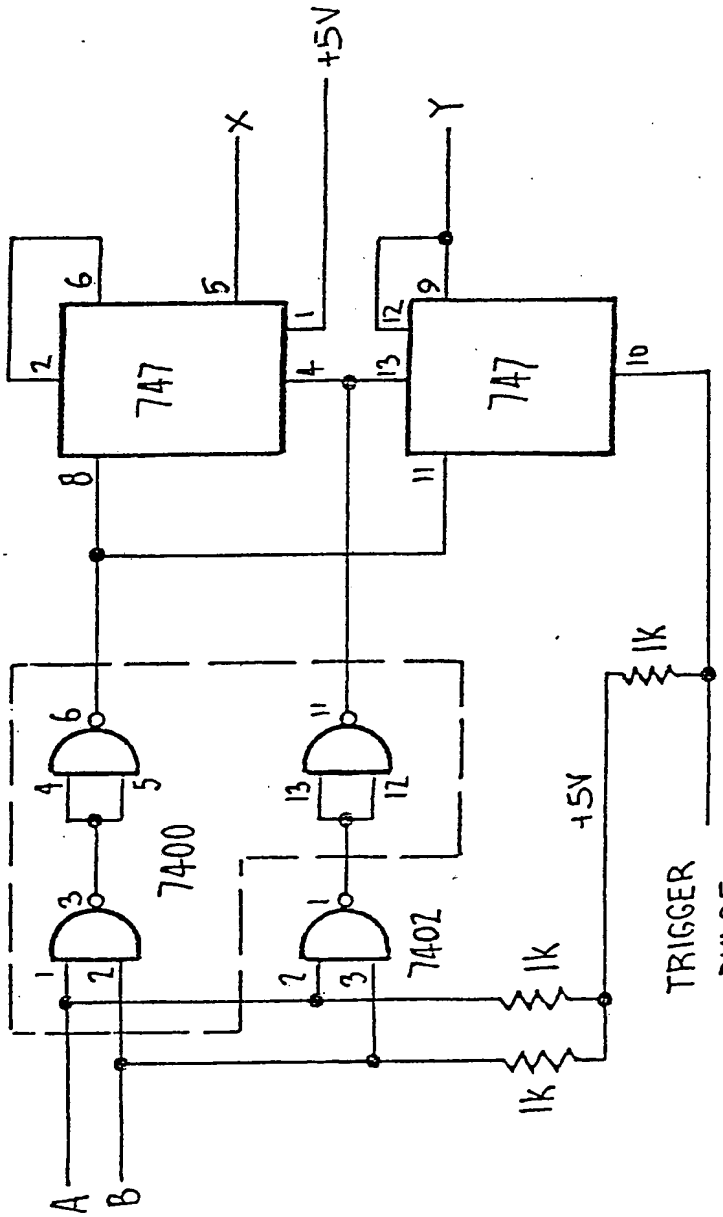


FIG. 7.



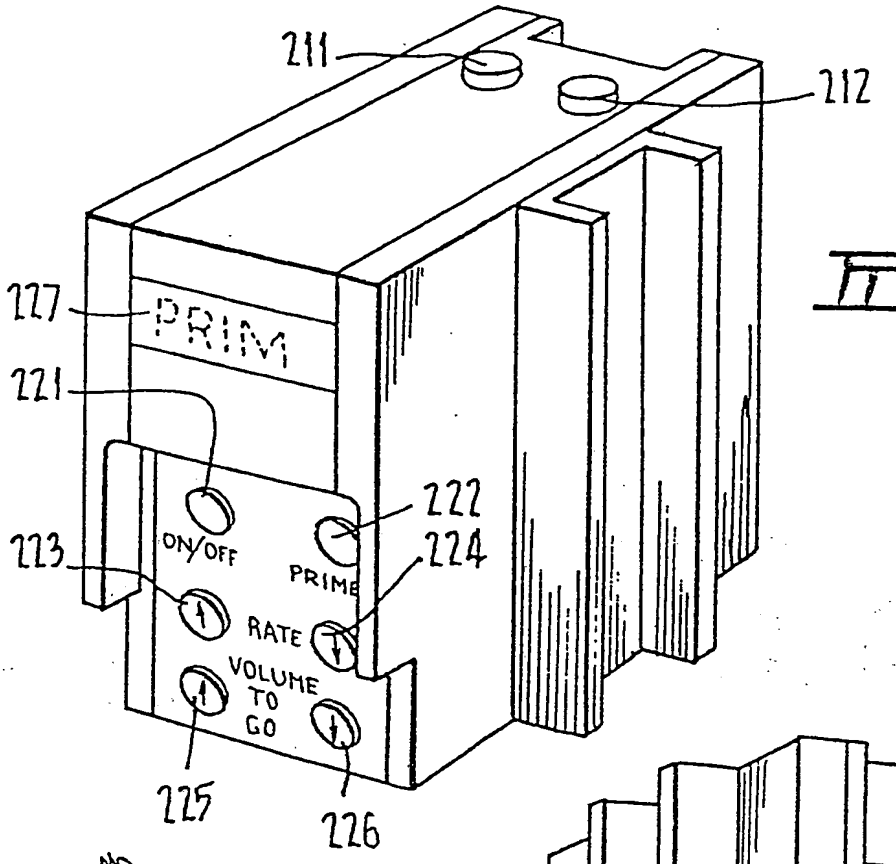


FIG. 8.

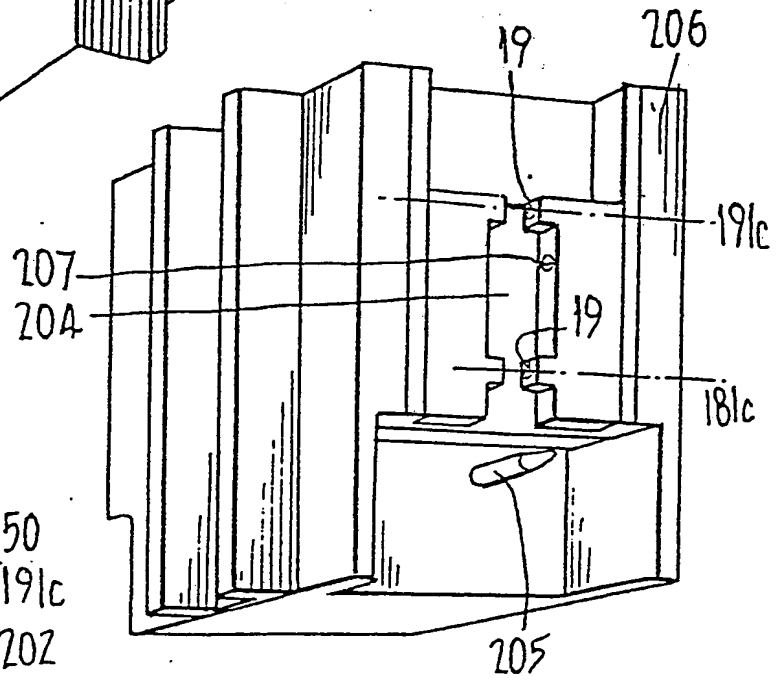


FIG. 9.

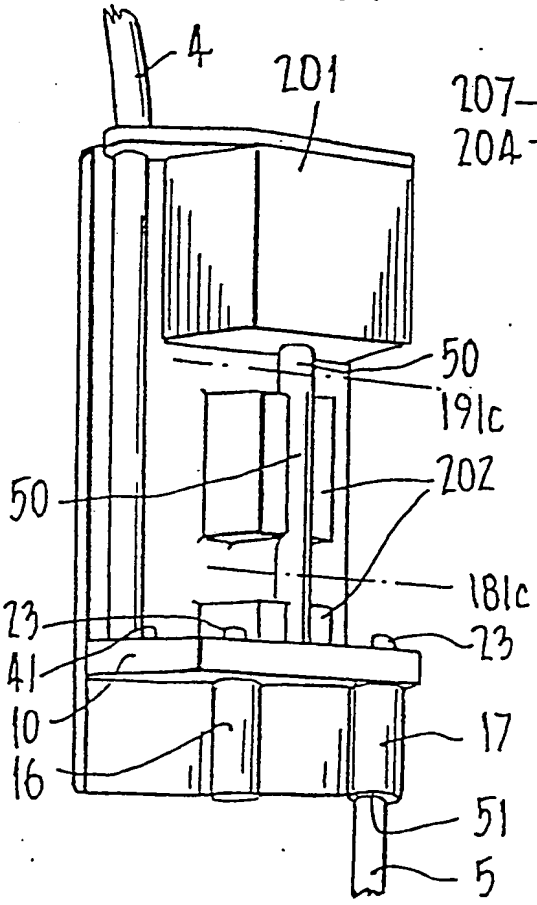
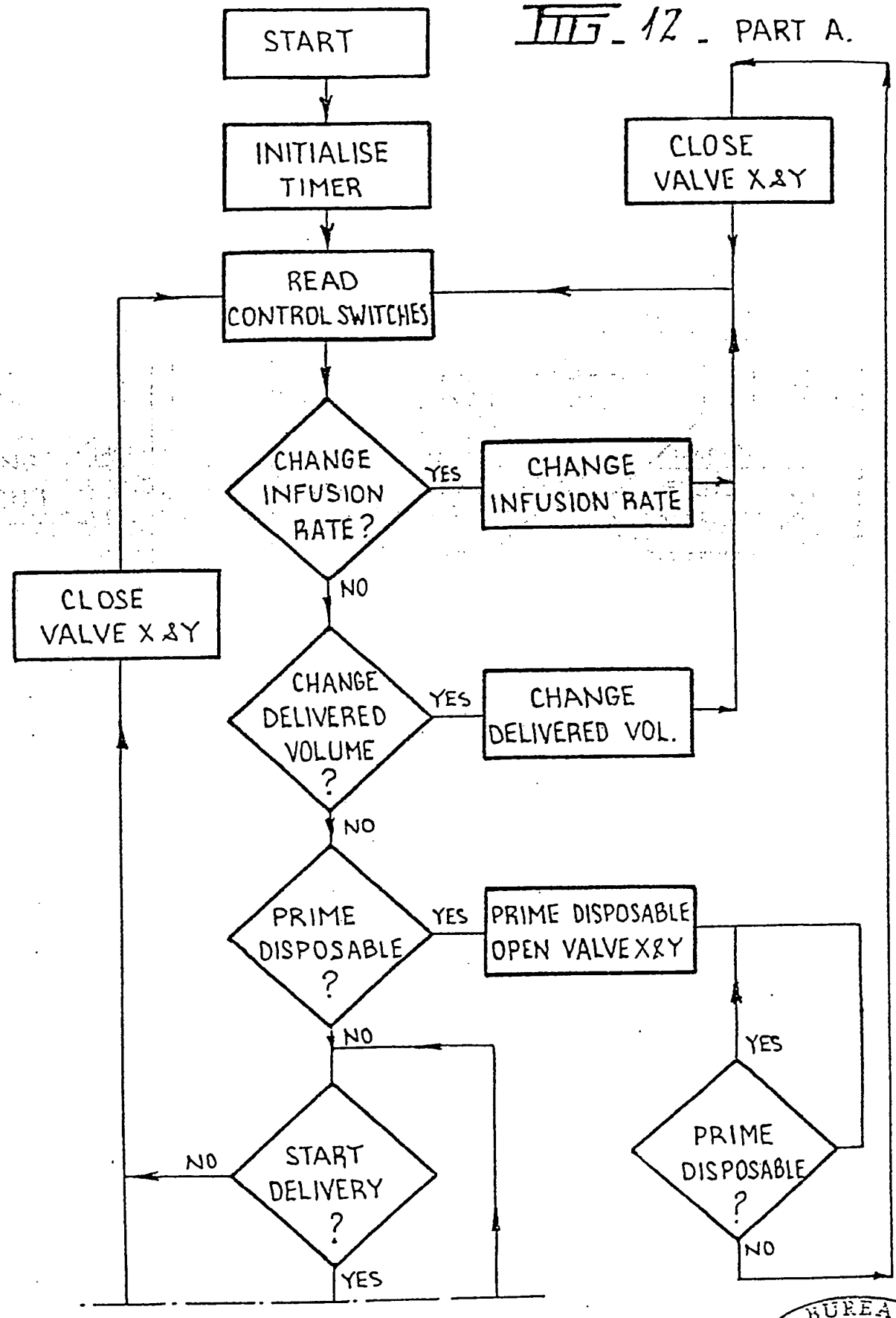


FIG. 10.

FIG. 12. PART A.



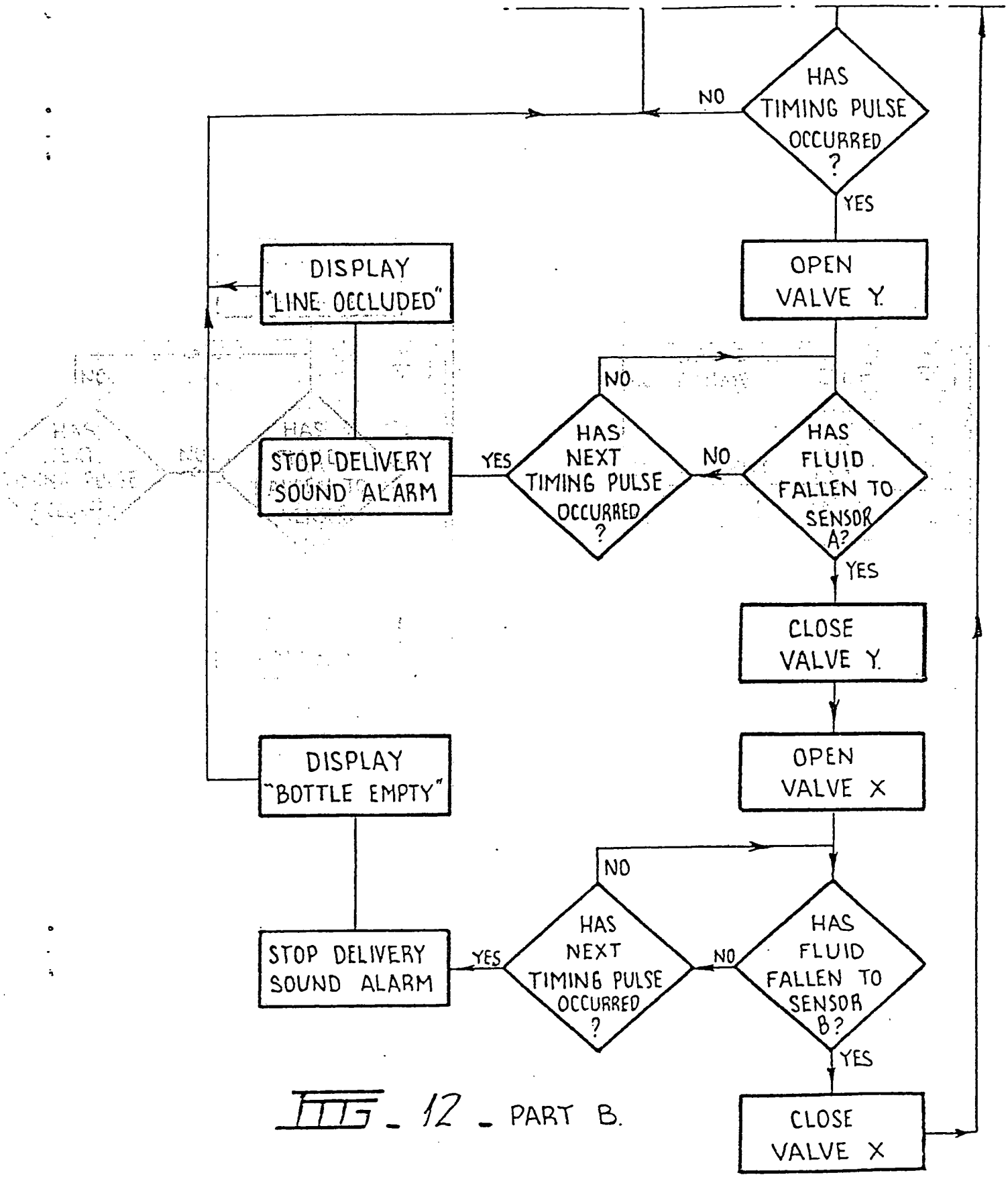


FIG. 12 - PART B.

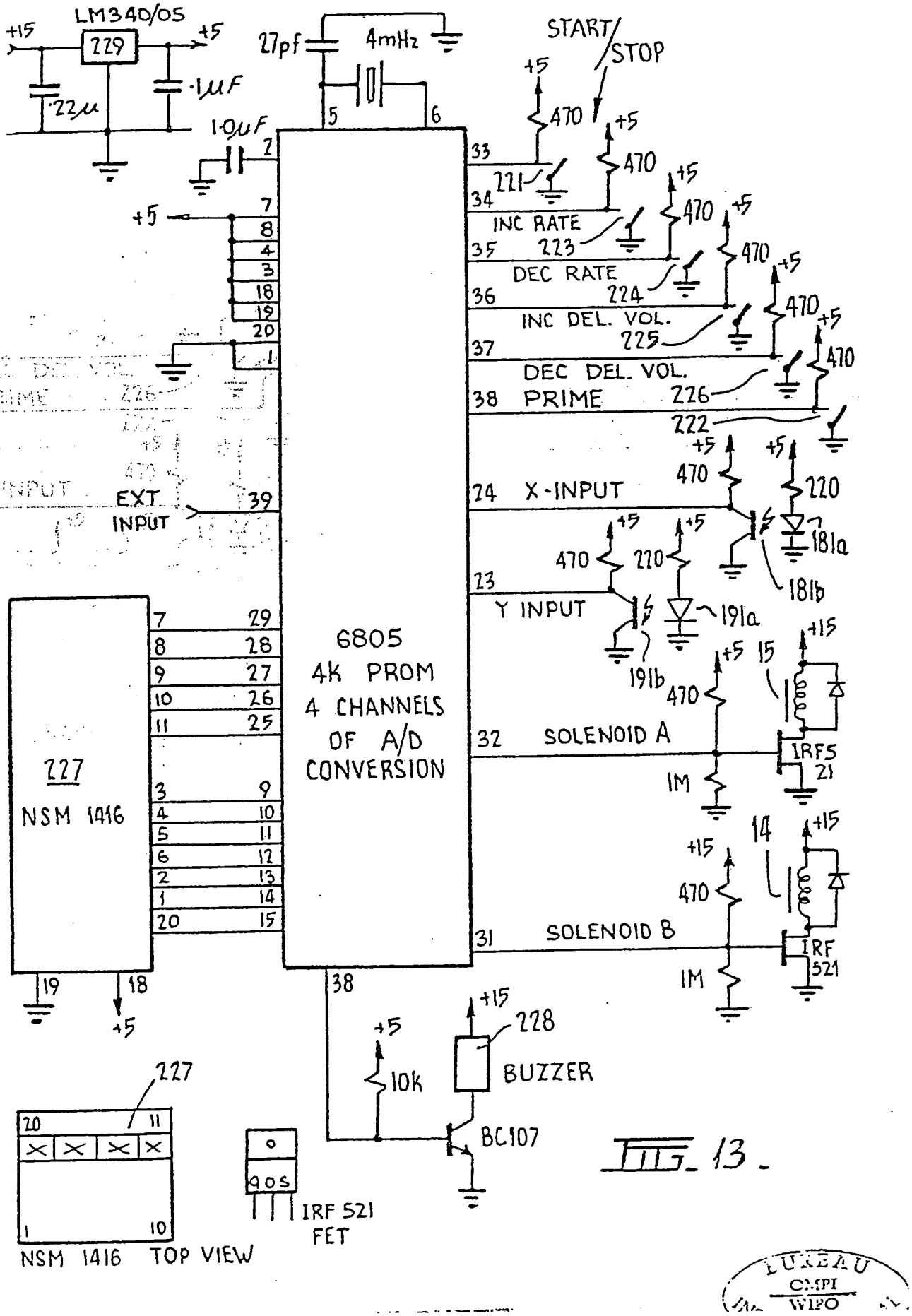


FIG. 13.

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 83/00012

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[3] A61M 5/14, G05D 7/06

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
INT. CL.[3]	A61M 5/14, G05D 7/03, 7/06
US CL.	128/214E

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

AU: IPC as above; Australian Classification 87.484, 56.5311, 83.9

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
A	US, A, 4297588 (HASTBACKA) 27 October 1981 (27.10.81)	
Y	US, A, 4275726 (SCHAEL) 30 June 1981 (30.06.81)	
A	US, A, 4223231 (SUGIYAMA) 16 September 1980 (16.09.80)	
X,Y	US, A, 4231366 (SCHAEL) 4 November 1980 (04.11.80)	
A	AU, B, 3633/51 (152081) (GEORGE FLETCHER & CO. LTD.) 6 September 1951 (06.09.51).	

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [3]	Date of Mailing of this International Search Report [3]
7 April 1983 (07.04.83)	11 April 1983 (11.04.83)
International Searching Authority [1]	**Signature of Authorized Officer [20]**
Australian Patent Office	A.S. Moore A.S. Moore.

Form PCT/ISA/210 (second sheet) (October 1981)